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RAC Application for FHCRC Protocol 1503
" A Phase I Study to Evaluate the Safety of Cellular Immunotherapy using genetically-modified Autologous CD20-specific CD8+ T cell Clones for Patients with relapsed CD20+ Indolent Lymphomas"

Non-Technical Abstract

Follicular Non-Hodgkin's lymphoma is a type of cancer that develops in lymph nodes. There is currently no treatment that cures follicular lymphoma, except possibly bone marrow transplantation. This clinical research study is an attempt to develop a new treatment for follicular lymphomas using the patient's own immune system. Patients with follicular lymphoma who have recurrent lymphoma after standard chemotherapy will be offered participation in this trial. Lymphoma patients who enroll on the trial will first have immune cells (T lymphocytes) collected from their bloodstream using a special type of machine, by a process called "leukapheresis". These T lymphocytes will be modified in the laboratory by transferring an artificial gene to them that will allow them to recognize a molecule called CD20 on the surface of the cancerous B lymphoma cells. The altered T lymphocytes will then be grown in the laboratory to large numbers over a period of roughly a month and then they will be frozen and stored. Patients will be treated with chemotherapy (cyclophosphamide, vincristine, and prednisone) every three weeks for six cycles of therapy (18 weeks total) after collection of their blood lymphocytes. At the end of the chemotherapy, the genetically altered T cells will be thawed and injected into the bloodstream of patients. Three separate infusions will be performed at two-week intervals with increasing numbers of T lymphocytes in each infusion. The T lymphocytes should bind to B lymphoma cells and kill them. Normal B-lymphocytes also express the CD20 molecule and will also be killed by the T cells, but normal B cells should reappear a few weeks or months after therapy. Twelve patients will be treated on this protocol. The first six will receive the T lymphocyte infusions alone and the last six will receive T lymphocyte infusions plus injection of a medicine called "interleukin 2" under the skin. The interleukin 2 is given to make the T cells live longer in the patient's body. After these treatments, patients will have blood tests, CT scans and other studies performed to see if the T cells have survived in the patient's body and if they killed the lymphoma cells.